

## RESEARCH ON ANABOLIC STEROID ABUSE

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Chemistry, Analytical

National Institute on Drug Abuse

National Institute of Child Health and Human Development

National Institute of Diabetes and Digestive and Kidney Disease

National Cancer Institute

National Institute of Arthritis and Musculoskeletal and Skin Diseases

### PURPOSE

The purpose of this announcement is to stimulate research and provide information to combat the misuse and abuse of anabolic steroids.

### HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Research on Anabolic Steroid Abuse, is related to the priority area of alcohol and other drugs. The specific goal stated in "Healthy People 2000" is the reduction of anabolic steroid use among male high school seniors to three percent. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, (telephone 202- 783-3238).

## ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, public or private, non-profit or profit-making organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply. Foreign organizations are not eligible for the R29 award.

## MECHANISMS OF SUPPORT

Support mechanisms include: Research Project (R01), small grant (R03), and First Independent Research Support and Transition (FIRST) Awards. Most investigator-initiated research are supported by research project grants. A research project grant is awarded to an institution on behalf of a Principal Investigator who has designed and will direct a specific project or set of projects. A research project grant can be renewed at intervals or supplemented through the formal submission and review process described below. An investigator may apply for a renewal (competing continuation) of an R01 grant by submitting an application for further support, including a report of progress and specific plans for future work. For information on the special requirements of the FIRST Award (R29) and the National Institute on Drug Abuse Small Grant (R03), contact the program staff listed at the end of this announcement.

## RESEARCH OBJECTIVES

The widespread abuse of anabolic-androgenic steroids [derivatives of testosterone possessing both androgenic (virilizing) and anabolic (tissue building) properties, hereafter referred to as anabolic steroids] is a significant public health concern. Anabolic steroids are taken to enhance athletic performance and/or physical appearance. Of particular concern is the widespread use of anabolic steroids by adolescents.

In order to develop effective prevention efforts for anabolic steroid abuse, epidemiological and etiological studies are needed to characterize: the nature and extent of anabolic steroid use among the variety of sub-populations who use these drugs, the motivations for use by these subgroups, and the effectiveness of urine testing and other discouragement policies. Prevention efforts also are hampered by the lack of credible information on the consequences of anabolic steroid abuse. Data are needed on both short- and long-term health effects; psychological effects, including the possibility of dependence; and social consequences. In addition, the use of injectable steroids raises the possibility of human immunodeficiency virus (HIV) transmission

through needle-sharing. Therefore, data are needed on the prevalence of needle-sharing among the sub-populations of anabolic steroid users.

Examples of research topics relevant to this announcement include:

- o Studies to determine whether or not there are significant neuropsychiatric and psychosocial effects of anabolic steroid use. Examination of the profile of behavioral activity, elucidation of underlying neurobiological effects.
- o Studies to determine both the long-term sequelae and short-term biomedical effects of use and abuse of anabolic steroids in both male and female adolescents and adults. The occurrence and nature of these effects should be correlated with such factors as the particular steroid(s) used, doses and dosing regimens, and duration of steroid exposure. Areas of interest include effects on the hypothalamic-pituitary-gonadal axis, peri- and post-pubertal growth and body composition, effects on hepatic lipid metabolism and lipoproteins, cancer etiology studies examining cellular and molecular effects on the liver and other susceptible tissues.
- o Determination of the incidence and prevalence of anabolic steroid use in the general population and its determinants. Characterization of anabolic steroid users, e.g., socioeconomic status, race, educational level, and participation in competitive athletics.
- o Prevention research with focus on the following objectives: (1) measurement of the extent of the drug problem, (2) identification of salient psychosocial risk factors, and (3) development and testing of the efficacy of theory-based preventive interventions.
- o Improved techniques for analytical testing of anabolic steroids. Studies of how sports organizations integrate anabolic steroid testing into overall drug testing programs.

## STUDY POPULATIONS

### SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition

under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5 Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

## APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions. The number and title of this announcement, "Research on Anabolic Steroid Abuse, PA-92-80," must be typed in item number 2a of the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. These forms may also be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone 301/496-7979.

The signed original and five permanent legible copies of the completed application must be sent to:

Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 240  
Bethesda, MD 20892\*\*

## REVIEW CONSIDERATIONS

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an initial review group (IRG) in accordance with established Public Health

Service Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the initial review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by the appropriate National Advisory Council. Only applications recommended for further consideration by the Council may be funded.

#### AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to the Institute/Center/Division. The following will be considered when making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

#### INQUIRIES

Direct inquiries regarding programmatic issues to:

Lynda Erinoff, Ph.D.  
Neuroscience Research Branch  
Division of Preclinical Research  
National Institute on Drug Abuse  
5600 Fishers Lane, Room 10A-19  
Rockville, MD 20857  
Telephone: (301) 443-6975

Gilman Grave, M.D.  
Chief, Endocrinology, Nutrition and Growth Branch  
Center for Research for Mothers and Children  
National Institute of Child Health and Human Development  
Executive Plaza North, Room 637  
Bethesda, MD 20892  
Telephone: (301) 496-5593

Philip F. Smith, Ph.D.  
Director, Endocrinology Research Program  
Division of Diabetes, Endocrinology, and Metabolic Diseases  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 621  
Bethesda, MD 20892  
Telephone: (301) 496-7341

Lea Sekely, Ph.D.  
Chemical Carcinogenesis Branch  
Division of Cancer Etiology  
National Cancer Institute  
Executive Plaza North, Room 700  
Bethesda, MD 20892  
Telephone: (301) 496-5471

Stephen Gordon, Ph.D.  
Musculoskeletal Diseases Program Director  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
5333 Westbard Avenue, Room 407  
Bethesda, MD 20892  
Telephone: (301) 402-3338

Direct inquiries regarding fiscal matters to:

Shirley Ann Denney  
Chief, Grants Management Branch  
National Institute on Drug Abuse  
5600 Fishers Lane, Room 8A-54  
Rockville, MD 20857  
Telephone: (301) 443-6710

E. Douglas Shawver  
Office of Grants and Contracts  
National Institute of Child Health and Human Development  
Executive Plaza North, Room 501  
Bethesda, MD 20892

Telephone: (301) 496-1303

Bruce Butrum

Grants Management Branch

Division of Extramural Activities

National Institute of Diabetes and Digestive and Kidney Diseases

Westwood Building, Room 649

Bethesda, MD 20892

Telephone: (301) 496-7467

Jean Cahill

Team Leader, Grants Administration Branch

National Cancer Institute

Executive Plaza South, Room 243

Bethesda, MD 20892

Telephone: (301) 496-7800, ext. 47

Diane Watson

Grants Management Officer

National Institute of Arthritis and Musculoskeletal and Skin Diseases

5333 Westbard Avenue, Room 403

Bethesda, MD 20892

Telephone: (301) 402-3352

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.279, 93.399, 93.849, 93.865, 93.846. Awards are made under authorization of the Public Health Service Act, sections 301 and 515 (42 USC 241 and 290cc) and administered under PHS grants policies and Federal Regulations 42 CFR 92 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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